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TAGS: ECON ETRD KIPR CA CBSA RCMP
SUBJECT: 2005 SPECIAL 301 REPORT FROM OTTAWA

¶1. (SBU) Summary: The regulatory picture on IPR has not changed much from earlier years, however Canada is moving to address many of the issues raised in the Special 301 submissions, even though results are unlikely to be visible before the end of April. On the headline issues of enforcement and WIPO ratification, there is incremental progress. Canada continues to inch toward WIPO ratification, with legislation due this spring. Departments responsible for IPR issues are also working to develop more effective cooperation on enforcement, but are not seeking greater enforcement powers at the border at this point. End Summary.

¶2. Econoffs met with representatives of FAC, Industry Canada, International Trade, Health Canada (HC), the Royal Canadian Mounted Police (RCMP), the Patent Medicine Prices Review Board (PMPRB), and the Canadian Border Services Agency (CBSA) to get their perspective on public submissions under Special 301 and the state of Canadian IPR law in general. Under the caveat that GOC finds the Special 301 process "deeply flawed", GOC officials responded to the points in the public submissions and gave an update on the status of intellectual property protection in Canada.

PhRMA Comments on Patents: GOC Response

¶3. (SBU) Data exclusivity: In December, Industry Canada published its proposed regulation to allow for longer data protection for patented medicines. At the same time, Health Canada has published complementary regulations that would circumscribe industry's ability to patent incremental innovations in existing drugs in a practice commonly known as "evergreening". Public comments on these regulations are due February 24th. Under the proposed rules, any Health Canada reliance on proprietary data in judging a generic application engages the protection period. HC is also proposing eight years of data exclusivity (three more years than the current five) and an extra six years for pediatric information. (Comment: Canadian patent-based industry reps have told us that in general their industry is happy with the extended data exclusivity and resigned to tighter controls on 'incremental innovation.' End Comment).

¶4. (SBU) International Trade Canada (ITCan) and Health Canada representatives disputed PhRMA's argument that brand-name manufacturers are legally vulnerable even when they comply with Canadian Notice of Compliance rules, saying that, while lawsuits are underway, no decisions have been reached and therefore it is too early to claim injury to the industry. They also commented that the pharmaceutical industry's claims of damages do not take into account the public costs of using NOC to delay legitimate generic drugs.

¶5. (SBU) Approval times: Health Canada officials described their efforts to streamline the approval process, noting their appreciation for FDA's advice and assistance. In the past year, Health Canada has hired new staff and adopted some of FDA's practices, such as assignment of a 'point person' to guide each submission through the process, and a move toward team reviews of submissions. Over 70% of the existing backlog has been eliminated, and Health Canada is aiming for on-time review in the near future.

¶6. (SBU) Price controls: Industry Canada reiterated that Canadian drug prices are in line with OECD prices and that price differentials also reflect the U.S. and Canadian GDP per capita differential of roughly 40 percent. (Comment: the first point is true by definition, since PMPRB generally sets prices at about the OECD median. The second point, which we have heard before, is dubious. Canada's per capita GDP is only about 20% below the U.S. figure; moreover, as drug costs are assumed by provincial health plans, it is hard to see why consumer disposable income is a factor. End comment.)

¶7. (SBU) Patent term restoration: Industry Canada and Health Canada officials acknowledged that this is a long-

term concern for PhRMA, and noted that PhRMA has had the ear of several senior government officials on the issue. Canada is not obligated under WIPO to offer patent term restoration and has no current plans to do so. Nevertheless, Industry and Health Canada officials understand that the lack of patent term restoration affects the investment climate for pharmaceutical companies. They are optimistic that the issue will become less pressing as the drug approval process in Canada becomes faster.

¶8. (SBU) Patent protection for higher lifeforms: Canadian courts have prohibited the patenting of higher lifeforms. The GOC has no plans to amend the Patent Act to overrule that decision. However, Industry Canada experts argue that, as several Supreme Court Justices pointed out, patenting of genes offers adequate if indirect protection to bioengineered life forms. Industry Canada experts noted that the biotech industry did not mention this issue in a recent meeting with Industry Minister Emerson.

¶9. (SBU) Access to medicines: GOC officials were puzzled by the PhRMA comments that "implementation must be in line with both parts of the WTO decision", as they believe this point is explicitly covered in both Canadian legislation and draft regulations.

Enforcement

¶10. (SBU) IT Canada and other GOC officials argue that the enforcement picture in Canada has measurably improved because of more effective coordination within the existing legal structure. The GOC has formed an interdepartmental working group consisting of ITCan, Industry Canada, Canadian Heritage, the RCMP, CBSA, Justice, and Public Safety and Emergency Preparedness Canada to coordinate enforcement of IPR laws. This working group has also met with industry associations, and GOC representatives are looking forward to meeting with U.S. officials on STOP.

¶11. (SBU) Since December of 2003, RCMP and CBSA are under the same minister, a development which has led to greater cooperation between the agencies. Both CBSA and RCMP representatives listed increased training and cooperation as major improvements in IPR enforcement in Canada. A recent 5-day workshop in Ontario drew over 100 participants, the largest workshop of its kind in North America. Upcoming training includes five two-day workshops in 2005 in other Canadian provinces. The RCMP officials also cited two continuing joint force operations, Castille in Montreal and Ocat in Toronto, which have already resulted in the seizure of large shipments of counterfeit goods. CBSA representatives highlighted their organization's efforts to streamline the procedure when they encounter counterfeit goods, including a standard process for contacting appropriate officials and determining whether it is GOC's priority to intercept a particular shipment.

¶12. (SBU) The CBSA representative explained that CBSA operates on a "risk management" basis using a list of government priorities, including IPR. Standard procedure now requires CBSA to detain suspect counterfeit goods until RCMP or other enforcement agencies are notified and can act. The CBSA representative also clarified that they can now look for shipments based on information received from other law enforcement agencies. Although there is no customs infraction as such if counterfeit goods are properly declared, the RCMP representative noted that they almost always break other laws. He cited as evidence of an improved enforcement climate the fact that goods no longer arrive at the Canadian border with declarations that explicitly identify them as counterfeit.

¶13. (SBU) Justice has also increased IPR training and has created a network for prosecutors to share case law and training information. In a positive development, 2004 saw higher criminal penalties in IPR cases. Two examples were a C$150,000 fine for a company guilty of selling electrical goods with fake UL labels and a case where two men were each fined C$25,000 and sentenced to 60 days in jail for selling illegal satellite equipment.

Copyright Reform

¶14. (SBU) There are no solid developments in Canadian copyright reform since the US-Canada experts' meeting in December 2004. Legislation covering WIPO ratification, access for higher education, ISP liability, and protection of photos among other issues is currently in the drafting process. Canadian Heritage expects a bill to be introduced in Parliament "in the first half of this year", but most likely not before May, and that the law will probably not pass this year. In the meantime, the government's reply to

the 2004 Heritage Committee report on copyright reform is due in April. This report will most likely reflect the substance of what the government plans to table.

¶15. (SBU) On the controversial 2004 filesharing decision, ITCan said that many observers considered that section 80 sub 2 of existing law seems to address the situation, and the Finckenstein decision came as a surprise to many officials. The December private copying tariff decision (which excluded embedded memory and harddrive copying from the private copying levy) is expected to be appealed to the supreme court. If upheld, GOC experts believe it would eliminate the legal basis for the filesharing decision, in which Judge Finckenstein relied upon the existence of the private copy levy as evidence that such copying was not an infringement. Econ officers reiterated that the best and simplest solution to the problem remains rapid ratification of the WIPO treaties.

Conclusion

¶16. (SBU) At this point, the regulatory picture on IPR has not changed much from recent years. However, Canada is moving to address many of the issues raised in the Special 301 submissions, even though results are unlikely to be visible before the end of April. While WIPO ratification remains a good way off, Canadian IPR officials are no longer claiming to us that existing Canadian law offers adequate protection; pressure from the Heritage Committee and the consternation generated by the filesharing decision make it likely that legislation will at last come before Parliament this spring as promised. While its fate under a minority government is hard to predict, there is strong support among both Liberals and Conservatives for WIPO ratification; other issues contained in the bill are likely to prove more controversial. On enforcement, it is hard to tell yet whether better enforcement training and coordination will lead to more seizures at the border; Post would like to hear from US firms about their experiences so that we can continue to engage the interdepartmental committee on the issue. Action request: GOC has requested advance notice of USTR's decision if possible; post would appreciate a heads up.

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